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GE Medical Systems

P.O. Box 414, W-709
Milwaukee, WI 53201
USA

K031637

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. ~~414~~ 544-3894
Summary prepared: May 2, 2003

Identification of Product(s): Innova 3100
Classification Name: Solid State X-ray Imaging System
Manufacturer: GE Medical Systems Europe
283, rue de la Minière
78530 Buc Cedex, France
Distributed by: GE Medical Systems, Milwaukee, WI

Marketed Devices: The Innova 3100 is substantially equivalent to the currently marketed Vascular Angiographic system Innova 4100 (K023178) and complies with the same or equivalent standards.
The SuperFast Gantry (InnovaTrace) with the capacitive sensor feature in the Innova 3100 system is substantially equivalent to the Innova 2000/Innova 2000S systems (K022322) for this feature.

Device Description: The Innova 3100 is designed to perform fluoroscopic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a Fiber Channel link to an acquisition equipment then to network (in using DICOM) for applications such as post-processing, printing, viewing and archiving. The Innova 3100 consists of an angiographic monoplaner positioner, a table, an X-RAY system and a digital detector.

The SuperFast Gantry (InnovaTrace) includes capacitive sensor technology and optimized collision avoidance software that permits an increase of pivot and C-arm speed of up to 20°/sec.

Materials:

All construction and materials are compliant with UL 2601.

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Design:

There are hardware and software redundancies to prevent single point failures that could cause unintended motion.

Energy Source: 480 VAC 50/60Hz.

Indications for Use:

The Innova 3100 system is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, and optionally, rotational angiography procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology.

Comparison with predicate

The system is substantially equivalent to the Vascular Angiographic System Innova 4100 system cleared under K023178.

The optional SuperFast Gantry (InnovaTrace) with capacitive sensor feature in the Innova 3100 system is substantially equivalent to the Innova 2000/Innova 2000S systems cleared under K022322 for this feature.

Summary of Studies:

Not applicable as Innova 3100 is considered substantially equivalent to Innova 4100 in terms of image quality and diagnostic capabilities.

Conclusions:

GE considers the system to be equivalent with the predicate devices. The system provides fluoroscopic images that are equivalent to the diagnostic capabilities of the predicate device images. The potential hazards, e.g., wrong measurements, misdiagnosis and increased gantry speeds are controlled by a risk management process including:

- A hazard identification
- A risk evaluation
- A Software Development and Validation Process



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
P.O. Box 414, W-400
MILWAUKEE WI 53201

Re: K031637
Trade/Device Name: Innova 3100 Digital
Fluoroscopic Imaging Systems
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic
x-ray system
Regulatory Class: II
Product Code: 90 MQB
Dated: May 23, 2003
Received: May 28, 2003

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

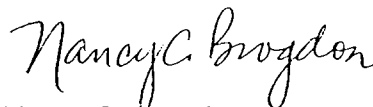
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K031637

Device Name: **Digital Fluoroscopic Imaging System – Innova 3100**

Indications for Use

The **Digital Fluoroscopic Imaging System** is indicated for use in diagnostic and interventional angiography procedures of human anatomy. It is intended to replace image intensifier fluoroscopic systems in all diagnostic or interventional angiography procedures. This device is not intended for mammography applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801-109)

OR Over-The-Counter Use _____

David H. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031637